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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/693,398      | 10/24/2003  | Lec A. Core          | 106586-172 US2      | 2513             |

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| WILMERHALE/BOSTON |      |            |
| 60 STATE STREET   |      |            |
| BOSTON, MA 02109  |      |            |

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|-----------------------------|--|
| EXAMINER                    |  |
| GETTMAN, CHRISTINA DANIELLE |  |

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
| 3734     |              |

|                   |               |
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| NOTIFICATION DATE | DELIVERY MODE |
| 12/06/2007        | ELECTRONIC    |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

michael.mathewson@wilmerhale.com  
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*Supplemental*  
**Office Action Summary**

Application No.

10/693,398

Applicant(s)

CORE, LEE A.

Examiner

Christina D. Gettman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-5, 13-18, 20, 21 and 26-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13-18, 20, 21 and 26-56 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn. As a result, this supplemental action is being mailed and is taking the place of the final rejection that was written on October 22, 2007.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 38-39 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Horzewski et al. (U.S. Patent No. 5,318,588). Horzweski et al. disclose the invention as claimed including a conduit for insertion into a body through which another device passes with two layers bonded together in a circumferential direction and the inner layer having a higher durometer than the outer layer (col. 7, line 40-41, 51-54; ref. 5-7, 11 and 14, Fig. 1A-1D), the conduit being an introducer sheath or a catheter (obvious variations of one another), and a medical device with an outer diameter greater than the inner layer diameter for insertion through the conduit (see bulge in Fig. 2A-2F) and wherein the conduit expands as the medical device passes through it.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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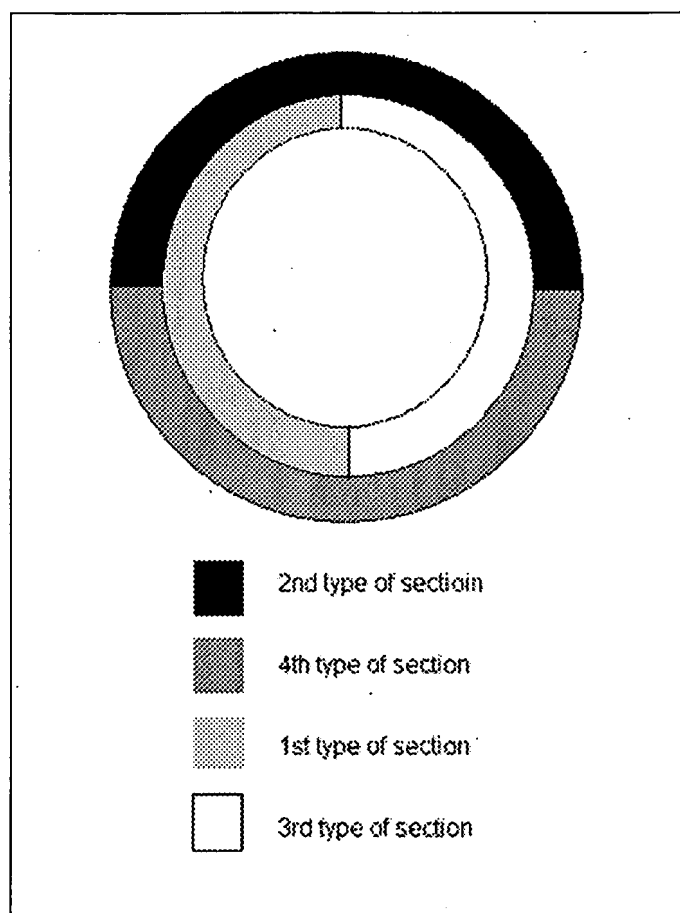
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 13-16, 20-21, 32, 37, and 45-52 are rejected under 35 U.S.C. 102(b)

as being anticipated by Horzewski et al. (U.S. Patent No. 5,318,588) in view of Leschinsky (U.S. Patent No. 6,346,092). Horzewski et al. disclose the invention as claimed including a conduit for insertion into a body through which another device passes with two layers bonded together and the inner layer having a higher durometer than the outer layer (col. 7, line 40-41, 51-54; ref. 5-7, 11 and 14, Fig. 1A-1D), the conduit being an introducer sheath or a catheter (obvious variations of one another), a medical device with an outer diameter greater than the inner layer diameter for insertion through the conduit (see bulge in Fig. 2A-2F) and wherein the conduit expands as the medical device passes through it, and a method of using the device (see Fig. 2A-2F). Horzewski et al. do not disclose a conduit having an inner layer that is discontinuous, by means way of a slot, and non-overlapping. Leschinsky teaches a layer that has slots (ref. 80, Fig. 3A) for the purpose of allowing the end (ref. 70, Fig. 3B) to expand. Therefore, it would have been obvious to one having ordinary skill in the art to have modified Horzewski et al. with an inner layer being discontinuous and non-overlapping in order to allow the conduit to expand radially as a medical device is passed through it. Although there are multiple slots in ref. 70, it would be obvious to make only one slot, ref. 80. Also, Leschinsky is obvious and is combinable with Horzewski because the inner layer of Horzewski is providing for the expansion of the conduit, which ref. 70 is doing in Leschinsky. The combination of Horzewski and Leschinsky also disclose a

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conduit that has third and fourth types of section in a circumferential direction. Although the layers are oriented with one layer outside the other layer, they are still comprised of first through fourth types of sections in a circumferential direction (see Fig. 1 below).



**Figure 1.** Diagram showing separation of section with the combination of Horzweski and Leschinsky. The 2nd type of section is adjacent to the 1st and 3rd types of section. The 1st and 3rd sections have the same elasticity and the 2nd and 4th sections have the same elasticity.

Claims 40-41 and 43-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. as applied to claims 39 and 38. Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent,

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blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. Stents, blood clot filter, and occluder are well-known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen. Howzeski et al. also disclose a conduit that has third and fourth types of section in a circumferential direction. Although the layers are oriented with one layer outside the other layer, they are still comprised of first through fourth types of sections in a circumferential direction (see Fig. 1 above).

Claims 7-11, 17-18, 33-36, and 53-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. and Leschinsky as applied to claims 4, 16, 1, 23, 19, 32, 39 and 38. Horzewski et al. disclose the invention substantially as claimed except for the inner layer having one of the other geometric formations to aid in expansion, the medical device being a stent, blood clot filter, or occluder, the device being foldable for delivery through the conduit and in a second manner different from the first manner for retrieval. The other geometric formations are obvious variation of having a slit and/or an overlapping section that would obtain the same results of expanding the inner layer of the conduit. Stents, blood clot filter, and occluder are well-

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known devices to be inserted through a conduit and into a lumen of a body such as a blood vessel. It is also well-known that these devices are folded into a smaller collapsed diameter so that they can be easily inserted into a delivery device. The expanded, deployed diameter of a stent, blood clot filter, and occluder is well-known to be larger than its initial diameter. Therefore, it would have been obvious to one having ordinary skill at the time of the invention to have modified Horzewski et al. and Leschinsky with a different geometric formation of the inner layer of the conduit and with the medical device being a stent, blood clot filter, or occluder in order to be inserted into a body lumen.

Claims 26-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. in view of Leschinsky. Horzewski et al. disclose an introducer sheath/catheter having two layers that are bonded to one another and the inner layer having means for allowing its diameter to expand. Howzeski et al. do not disclose a conduit having an inner layer that is discontinuous, by means way of a slot, and non-overlapping. Leschinsky teaches a layer that has slots (ref. 80, Fig. 3A) for the purpose of allowing the end (ref. 70, Fig. 3B) to expand. Therefore, it would have been obvious to one having ordinary skill in the art to have modified Horzewski et al. with an inner layer being discontinuous and non-overlapping in order to allow the conduit to expand radially as a medical device is passed through it. Although there are multiple slots in ref. 70, it would be obvious to make only one slot, ref. 80. Also, Leschinsky is obvious and is combinable with Horzewski because the inner layer of Horzewski is providing for the expansion of the conduit, which ref. 70 is doing in Leschinsky.

Claims 26-31 are further rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski et al. and Leschinsky in view of Querns et al. (U.S. Patent No. 5,944,691). Horzewski et al. and Leschinsky do not disclose a method of how the sheath/catheter is formed. Querns et al. teach the method of co-extrusion (col. 3, line 43-54) for the purpose of forming a two-layered sheath/catheter. It is also an obvious well-known variation to use a method of dipping instead of co-extrusion to form the sheath/catheter. Therefore, it would have been obvious to have made the sheath/catheter by either co-extrusion or dipping in order to form a two-layered sheath/catheter.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-37 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's arguments filed August 7, 2007, have been fully considered but they are not persuasive. Applicant argues that Horzewski does not teach or suggest a conduit with two layers bonded together wherein the inner layer has a higher durometer than the outer layer. Examiner respectfully disagrees.

As mentioned above in the 35 USC 102(b) rejection, Horzewski does disclose two layers of the conduit having two durometers. The inner layer of the conduit has a higher durometer and the outer layer of the conduit has a lower durometer. The layers are in a circumferential direction since the layers are in a circular shape, as shown in Fig. 1B. There is no limitation in the claims of the different durometer materials alternating within a circumferential direction in a single layer.



***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sherry (U.S. Patent No. 6,368,238), Taylor et al. (U.S. Patent No. 5,938,587), and Stone (U.S. Patent No. 6,312,443) all disclose expandable sheaths/catheters to be used for inserting a medical device into a body lumen.\

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

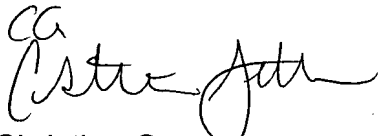
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina D. Gettman whose telephone number is 571-272-3128. The examiner can normally be reached on Monday-Friday 7:15 am to 3:45 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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SUPERVISORY PATENT EXAMINER